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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/518,076	03/03/2000	Leland Shapiro	114232.109	5437

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PATENT ADMINSTRATOR  
KATTEN MUCHIN ZAVIS ROSENMAN  
525 WEST MONROE STREET  
SUITE 1600  
CHICAGO, IL 60661-3693

EXAMINER
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HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

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DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/518,076

Applicant(s)

SHAPIRO, LELAND

Examiner

Myron G. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1- 39 is/are pending in the application.
- 4a) Of the above claim(s) 9- 11 and 16- 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1- 8 and 11- 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 21. 6) ☒ Other: *Notice to Comply*.

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I, species V in Papers No. 18 and 24 is acknowledged. The traversal is on the ground(s) that it would not be a burden to search all the claims because they are in the same class /subclass. This is not found persuasive because each of the groups of compounds is a distinct chemical structure or drawn to methods that treat different diseases/conditions (treating any STD with compounds other than AAT).

Claims 9- 11 and 16- 39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

### ***Information Disclosure Statement***

A signed and initialed copy of IDS paper # 21 is enclosed. It is noted that paper #10 (your mail date 29 August 2001) is noted as a Supplemental IDS; however, there is no PTO-1449 included and there is no evidence of a prior IDS in or on the file wrapper. The Office would like to know if these references are on paper #21 and if there is an earlier IDS.

### ***Drawings***

Applicant is reminded of the PTO-948 sent in prior communication.

### ***Sequence Requirements***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

See at least page 3, starting on line 8 and page 6, lines 2 and 3.

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

### ***Claim Objections***

Claim 15 is objected to because of the following informalities: punctuation errors in the claim, see at least the junction of the first and second named species.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 5, 6, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what is meant by "disease arising from a herpes virus infection." It is not clear that all the named conditions in claim 3 are the direct result of a herpes infection. In claims 5 and 6 it is not clear if these are steps that are part of the method or if it is akin to a product by process claim for the agent used. Claims 5 and 6 are for the purpose of this office action treated as akin to a product by process and not a method step. It is not clear in claim 11 where the dose is applied.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5- 8, 11- 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Lezdey (US 5,532,215).

Lezdey teaches a method to treat a subject suffering from a herpes virus infection, eczema or related conditions with an AAT compound by topical or systemic

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dosing at about 1mg/kg body weight (column 5, lines 16- 33, column 6, line 32 – column 7, Example 1, column 12, lines 10- 12, Claims 1 and 2). Lezdey teaches that AAT is a serine proteinase inhibitors that is in the subgroup called serpins (column 3, lines 39-41) and that alpha 1- protease inhibitor (alpha 1- PI) is another name for AAT (column 5, line 19).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 4 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gyorkos (US 5,618,852).

Gyorkos teaches AAT related compounds can be used to treat conditions that are caused by an imbalance in the level of alpha 1- PI including invasion of malignant tumors and related conditions (column 1, lines 28- 35). While Gyorkos does not name all the conditions as per the claims, one of skill in the art would realize the range of conditions that can be treated by the method of Gyorkos.

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Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lezdey as applied to claims 1- 3, 5- 8, 11- 14 above, and further in view of Gyorkos (US 5,891,792).

Lezdey as discussed above teaches the use of AAT to treat herpesvirus infection.

Lezdey does not teach related compounds that have AAT-like activity.

Gyorkos teaches a series of compounds including (Benzyloxycarbonyl)-L-valyl-N-[1-(2-[-(3-methylbenzyl)-1,3,4-oxadiazolyl]carbonyl)-2-(S)-methylpropyl]-L-prolinamide that are serine proteinase inhibitors that are low molecular weight, high stability, stability in physiological conditions, is a serpin, and can be formulated as a pharmaceutical (column 11, line 60- column 12, line 9, column 13, line 34- column 14, line 47, and Example I). Gyorkos also teaches that these compounds are inhibitors of alpha-1 protease (column 1, lines 8- 53)

One of ordinary skill in the art at the time of the invention would have known that the compounds described by Gyorkos had the activity exhibited by mammalian alpha-1-antitrypsin that are required to meet the requirements of the method of Lezdey. One of ordinary skill in the art at the time of the invention would have known the benefits of the compounds taught by Gyorkos as discussed above and would have used them in the method of Lezdey.

Thus, it would have been *prima facie* obvious to use the compounds of Gyorkos including (Benzyloxycarbonyl)-L-valyl-N-[1-(2-[-(3-methylbenzyl)-1,3,4-

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oxydiaxoly]carbonyl)-2-(S)-methylpropyl]-L-prolinamide knowing that it has AAT activity in the method of Lezdey with the expectation of success.

### **Conclusion**

No claim is allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Myron G. Hill  
Patent Examiner  
May 1, 2003



JAMES HOUSEL 5/5/03  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600